

**SH 18 WHITENING - hydroquinone cream**  
**International Beauty Exchange**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

Hydroquinone 2%

Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%

For external use only

On children under 12 years of age unless directed by a doctor

Avoid contact with eyes.

Skin Lightener

For the gradual fading of dark areas in the skin such as freckles, age and liver spots

Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor

If swallowed, get medical help or contact a Poison Control Center right away

WATER, GLYCERYL STEARATE CITRATE, CETOSTEARYL ALCOHOL, GLYCERIN, ISOPROPYL MYRISTATE, ALLANTOIN, ASCORBIC ACID, SODIUM METABISULFITE, SODIUM LAURYL SULFATE, DISODIUM EDTA, DISODIUM, METHYL PARABEN, PROPYL PARABEN, CHLOROCRESOL

<b>Drug Facts</b>		<ul style="list-style-type: none"> <li>Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.</li> </ul>
<b>Active ingredients</b> Hydroquinone 2% ..... Skin Lightener Ethylhexylmethoxycinnamate 0.5%..... Sun Screen	<b>Purpose</b> Skin Lightener Sun Screen	
<b>Uses</b> Gradually fades skin discolorations such as age spots, freckles, scars.		<b>Directions:</b> <ul style="list-style-type: none"> <li>Clean your skin with <b>SH-18</b> soap. Adult and children over 12 years old apply cream evenly to your skin twice a day or as directed by a doctor.</li> <li>Sun exposure should be limited by using a sunscreen agent, a sun blocking agent or protective clothing to cover skin after treatment is completed, to prevent darkening from reoccurring.</li> </ul>
<b>Warnings:</b> <ul style="list-style-type: none"> <li>For external use only</li> </ul>		
<b>Do not use:</b> <ul style="list-style-type: none"> <li>On children under 12 years of age unless directed by a doctor.</li> <li>This product for the prevention of sunburn.</li> </ul>		
<b>When using this product</b> <ul style="list-style-type: none"> <li>Avoid contact with eyes.</li> </ul>		<b>Inactive ingredients:</b> Water (Aqua), Glyceryl Stearate, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Fragrance (Parfum), Allantoin, Ascorbic Acid, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Sodium Citrate, Methylparaben, Propylparaben, p-Chloro-m-Cresol.

**SH 18 WHITENING**  
 hydroquinone cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 129-110
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1 g in 50 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	.25 g in 50 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLOROCRESOL (UNII: 36W53O7109)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66 129-110-31	50 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	01/01/2011	

**Labeler** - International Beauty Exchange (966261273)

**Establishment**

Name	Address	ID/FEI	Business Operations
JABONES PARDO SA		4620 18250	manufacture

Revised: 6/2011

International Beauty Exchange